Budget Impact of Medicaid Section 1115 Demonstrations for Early HIV Treatment

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A state-transition model of HIV disease was used to project the costs to Medicaid, Medicare, and AIDS Drug Assistance Programs of proposed Section 1115 Medicaid demonstration projects for the early treatment of HIV-infected patients in Georgia and Massachusetts. Neither demonstration project was projected to meet 5-year tests of no increase in Federal spending and in both States average patient costs to all payers were highest in the first year after enrollment. In assessing expanded health care access for patients with chronic diseases, government payers should consider overall budgetary effects and separately analyze costs for each year's enrollees to avoid creating incentives to cap enrollments.

INTRODUCTION

Section 1115 Demonstrations

Section 1115 of the Social Security Act permits the Secretary of the Department of Health and Human Services to waive certain portions of the Act in order to authorize demonstration projects for up to 5 years. Section 1115 demonstrations can be an attractive option for Medicaid expansions because they allow States to offer a tailored package of benefits for specific populations and to avoid open-ended financial commitments (Milligan, 2001). These demonstrations have been used for targeted Medicaid expansions that fill gaps in insurance coverage for selected services (including family planning services and prescription drug discounts) or specific populations (Lambrew, 2001). More recently, two new initiatives by CMS—the Health Insurance Flexibility and Accountability (HIFA) initiative (6 approved, 3 pending) and Pharmacy Plus (4 approved, 9 pending) have resulted in 22 new demonstration applications (U.S. Department of Health and Human Services, 2003a,b).

An important requirement for Section 1115 demonstration projects is that they meet a test of no impact on federal spending. For Medicaid demonstration projects, this is defined as no increase in Federal spending for the Medicaid Program over and above what would be expected in the absence of the demonstration during the proposed waiver period, which is usually 5 years (*Federal Register*, 1994). A Medicaid expenditure ceiling is calculated by comparing projected with waiver to without waiver costs, and the assumptions used to determine these forecasts are the subject of negotiation between the States and Federal reviewers. Difficulties in determining accurate projections have been noted by the U.S. General Accounting Office

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(1995, 2002) in two reports that each reviewed four approved demonstration applications and found significant problems in the determination of budget impact to Medicaid. The involvement of the CMS Office of the Actuary has varied, and the U.S. General Accounting Office (2002) recommended that actuaries become more involved in the waiver process. Even if there is agreement on financial projections, however, the requirement for no impact on Federal spending for the Medicaid Program does not recognize the potential impact of Section 1115 demonstrations on other Federal programs. The National Governors Association (2002) has recommended that States be permitted to consider budget impact across Federal programs.

Early Treatment of HIV-Infected Patients

We used a computer simulation model to test the Federal budget impact of two Section 1115 Medicaid applications for demonstration projects that were proposed to CMS in 2000 for the early treatment of HIV-infected patients over and above what would be expected in the absence of the demonstrations. To be eligible for Medicaid, HIV-infected patients must meet a definition of disability that generally requires the presence of AIDS-defining symptoms (Buchanan and Smith, 1994; Westmoreland, 1999). Since the rationale for early initiation of drug treatment is to avoid these symptoms, Medicaid's policy creates a catch-22 for HIV-infected patients who do not yet meet the disability eligibility requirement (Laurence, 2001). The Federal response to this gap in Medicaid eligibility was to establish State-level AIDS Drug Assistance Programs (ADAPs) through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. ADAP funds in many States are supplemented from the States' general revenues, but at varying levels. There are 13 States that have reported restricted access to program enrollment or to antiretroviral drugs due to inadequate budgets in 4 of the last 6 years (fiscal years 1996-2001) (Aldridge et al., 2002). Moreover, Federal ADAP funds do not cover important non-drug services that are required for effective antiretroviral therapy, such as HIV RNA (viral load) testing and physician office visits.

Section 1115 Demonstration Applications

We reviewed Section 1115 demonstration applications submitted to CMS by the State of Georgia on October 30, 2000, and by the Commonwealth of Massachusetts on April 7, 2000. The Georgia application was designed to meet a 5-year Medicaid budget impact requirement on a stand-alone basis. The Massachusetts application was to expand a previously approved Section 1115 demonstration project for the State's entire Medicaid Program during its remaining 2 years, and it did not have to meet a stand-alone budget impact requirement. Instead, its cost was required only to not exceed the budget surplus that had been previously identified for the entire Massachusetts Medicaid demonstration project.

Table 1 summarizes major elements of the demonstration projects described in the two applications. Because patients with advanced HIV disease were more likely to have already qualified for Medicaid on the basis of disability, both programs were projected to recruit primarily earlier-stage patients: 90 percent of Georgia enrollees were expected to have CD4 cell counts[1] greater than 200/μL, and two-thirds of Massachusetts enrollees were projected to

[1] A CD4 cell count is the most commonly used laboratory test for assessing the status of the immune system in HIV-infected patients. As the CD4 cell count declines, the risk of developing opportunistic infections increases.

Table 1

Section 1115 Medicaid Demonstration Applications for HIV Treatment, by State

Characteristic	Georgia	Massachusetts
	Percent	
Stage of Disease		
HIV	90.0	66.7
AIDS	*10.0	33.3
Current Program Participation		
New Enrollees	60.0	66.7
ADAP Enrollees[1]	40.0	33.3
Financial Eligibility	[2]<235 FPL	[2]<200 FPL
Year 5 Enrollment	6,500 Individuals (Capped)	1,584 Individuals
Benefits		
Antiretroviral Drugs	Covered by ADAP (85% Treated According to Federal Guidelines)	Covered by Medicaid
Limitations	Care Limited to HIV Centers of Excellence	Nursing Home and Non-Emergent Transportation Excluded

*CD4 cell count <200/μL.

[1] Enrolled in AIDS Drug Assistance Program (ADAP) in the absence of a waiver.

[2] The Federal poverty level (FPL) was $8,240 for an individual.

SOURCE: Georgia and Massachusetts Section 1115 demonstration applications, 2000.

be HIV-infected patients who had not yet progressed to an AIDS diagnosis. The remainder were patients who met the criteria for an AIDS diagnosis (e.g. CD4 cell counts less than 200/μL), but were not eligible for Medicaid based on disability and/or income.

Both programs were targeted to enroll newly identified untreated Medicaid enrollees who were not currently in the health care system and individuals already in the health care system who would have been enrolled in ADAP in order to cover drug costs if the demonstration projects were not available. In 1999, the Georgia ADAP was 90 percent funded by Federal contributions and spent on average $602 per month per enrollee; the Massachusetts ADAP was 77 percent funded by Federal contributions and spent on average $843 per month per enrollee (Doyle and Jefferys, 2000). Income eligibility requirements in both demonstration applications were similar, but there was an important distinction between the States' enrollment projections. Enrollment in the Georgia demonstration project was capped at 6,500 individuals, a level that the State projected would be reached at the beginning of the fourth year of the program. Thereafter, new enrollees could be admitted only to replace those who died or otherwise became ineligible for the program. In contrast, enrollment in the Massachusetts demonstration project was projected to be much smaller, growing from approximately 1,100 in the first year to approximately 1,600 at the beginning of the fifth year.

Another difference between the demonstration projects that affected their cost to Medicaid was how they chose to cover antiretroviral drugs. Georgia's application excluded antiretroviral drugs from the benefits to be provided by Medicaid. The State's ADAP would provide these drugs to all waiver program enrollees, 85 percent of

whom were expected to receive treatment in accordance with Federal guidelines. By maintaining a separately funded program to pay for antiretroviral drugs, which represented the largest cost element for earlier treatment of HIV-infected patients, Georgia was able to limit the projected increase in cost to Medicaid.

According to the Georgia application, future savings from avoiding hospitalization and other costs associated with untreated disease resulted in projected 5-year savings to Medicaid of $4.1 million. The projections also reflected expected savings due to higher quality care and shorter hospital lengths of stay (LOS), because patients in the demonstration project were required to receive their care at HIV Centers of Excellence. These Centers of Excellence were to be designated by the State in response to a Request for Proposals on the basis of their ability to serve the HIV-positive population according to criteria described in the application. Using the 1999 Federal Medicaid cost-sharing ratio for Georgia of 60.47 percent (*Federal Register*, 1997), $2.5 million of the projected savings would have accrued to the Federal Medicaid budget.

Massachusetts chose to cover all of the possible health care services for enrollees through Medicaid, including antiretroviral drug therapy, with the exception of nursing home care and transportation for non-emergent care. In its application, Massachusetts projected a 5-year cost to Medicaid of $75.2 million, of which $37.6 million would have accrued to the Federal Medicaid budget using the 1999 Federal Medicaid cost-sharing ratio for Massachusetts of 50 percent (*Federal Register*, 1997). Savings to offset the cost increase during the first 2 years had already been identified elsewhere in the Massachusetts Medicaid system, as part of the previously approved Section 1115 demonstration project for the State's entire Medicaid Program.

METHODS

Waiver and No Waiver Scenarios

For each State, we projected annual health care costs for patients who were enrolled in the demonstration project (waiver scenario) and for the same patients if the demonstration project were not available (no waiver scenario). In the Georgia waiver scenario we assumed that 85 percent of patients would be treated in accordance with current Federal guidelines (U.S. Department of Health and Human Services, 2001), as indicated in the Georgia demonstration application. For the remaining patients, antiretroviral therapy costs were assumed to be incurred when their CD4 cell counts fell below 200/μL. In the Massachusetts waiver scenario, we assumed that all patients received treatment in accordance with current Federal guidelines.

In the Georgia no waiver case, we followed the Georgia demonstration application assumption that one-quarter of patients already in the health care system would receive early treatment in accordance with current Federal guidelines, and the remainder would receive therapy only if they had CD4 cell counts below 200/μL. We altered this assumption in a sensitivity analysis to test the impact if all patients in the health care system received early treatment in accordance with current Federal guidelines. In the Massachusetts no waiver scenario, we assumed that all of the patients who were already in the health care system would receive care in accordance with current Federal guidelines.

In both States we assumed that the remaining patients did not enter the health care system until their CD4 cell counts fell below 200/μL or they experienced their first opportunistic infection according to the model, and those who enrolled in Medicaid received antiretroviral therapy. This represented 60 percent of patients in the Georgia no waiver scenario and two-thirds of patients in the Massachusetts no waiver scenario. The applications assumed no differences in initial stage of disease between these patients and those already in the health care system, and we retained this assumption.

Cost Simulation Model and Sensitivity Analyses

Average annual costs per surviving patient, patient survival rates, and the incidence of opportunistic infections for each treatment strategy were estimated using a computer-based, state-transition simulation model of the progression of HIV disease. This model has been used previously to estimate the cost effectiveness and costs to State payers of antiretroviral therapy (Freedberg et al., 2001; Schackman et al., 2001). The advantage of using a state-transition model is that the impact of program eligibility on treatment initiation and the resulting changes in cost can be simulated at the patient level. This means that the frequency of clinical events (such as specific opportunistic infections or death) can be determined and that drug and non-drug costs can be assigned to the appropriate payer in each scenario. Estimates from the model of patient outcomes for each treatment initiation strategy were then used to project annual costs for all patients entering the waiver and no waiver scenarios in the first year. The process was repeated for patients entering in each subsequent year in order to obtain total 5-year costs.

The efficacy of antiretroviral therapy was based on the results of clinical trials, and a sensitivity analysis was performed to test the impact of assuming lower efficacy rates based on those reported in a Medicaid population (Lucas, Chaisson, and Moore, 1999). Drug costs were average wholesale drug prices (AWP) published in the *1999 Red Book* (Drug Topics, 1999), less a 20-percent discount for government payers. This was the discount that was assumed for antiretroviral drugs in the Massachusetts waiver application. Non-drug costs were derived from charges reported in the AIDS Costs and Service Utilization Survey (ACSUS) and the Boston Medical Center cost accounting system and adjusted for cost differences between the States, as previously described (Schackman et al., 2001). Non-drug costs in the model were input separately for acute opportunistic infections (by type of infection), for chronic HIV/AIDS (by stage of disease and history of opportunistic infections), and for the last month of life (by cause of death). The resulting cost estimates were comparable to costs for early-stage patients estimated by the HIV Cost and Utilization Study investigators from ACSUS charges and provider reports of payments received (Bozzette et al., 1998; 2001), and to costs reported for early-stage Maryland Medicaid patients (Fakhraei, Kaelin, and Conviser, 2001). Unfortunately, these three studies did not provide sufficient detail on non-drug costs to be used directly as inputs into the model.

For Georgia, we adjusted non-drug costs as indicated in its waiver application. In the Georgia waiver scenario non-drug costs were reduced by 20 percent to reflect the State's expectation of improved quality of care associated with the Centers of Excellence. In the Georgia no waiver scenario, the application increased non-drug

costs by approximately 35 to 100 percent (depending on stage of disease) to reflect the longer hospital stays experienced by Georgia Medicaid recipients compared to the experience reported in Maryland (Gebo et al., 1999). The impact of these assumptions were tested in sensitivity analyses.

All costs were expressed in constant 1999 U.S. dollars, the last full year before the demonstration applications were submitted. Costs were allocated between Federal and State payers using cost-sharing ratios that were in effect for these programs in 1999 (Doyle and Jefferys, 2000; *Federal Register*, 1997). An additional category, "other" costs, occurred only in the no waiver scenario and primarily represented the non-drug costs for patients who were not yet enrolled in Medicaid (including patients enrolled in ADAP). Depending on the State, most of these costs would be incurred at the State or county level by ADAP expansion programs or as indigent care. Some of the costs might also be paid for with other Federal funds provided by the Ryan White CARE Act or community health center grants (Levi and Kates, 2000), and it is also possible that some of the costs would be incurred by employer health plans.

Program Eligibility

In our simulations of the Georgia and Massachusetts waiver scenarios, all patients were enrolled in Medicaid at the beginning of the year in which they entered the program. In the no waiver scenario simulations in both States, patients already in the health care system were initially enrolled in ADAP. In the Georgia no waiver scenario, patients subsequently enrolled in Medicaid according to assumptions provided in the demonstration application. In the Massachusetts no waiver scenario, each simulated patient was enrolled in Medicaid at the time that his or her first opportunistic infection occurred according to the model. In all scenarios, Medicaid patients were assumed to become eligible for dual Medicare/Medicaid enrollment 29 months after their first opportunistic infection occurred as predicted by the model (Westmoreland, 1999).

RESULTS

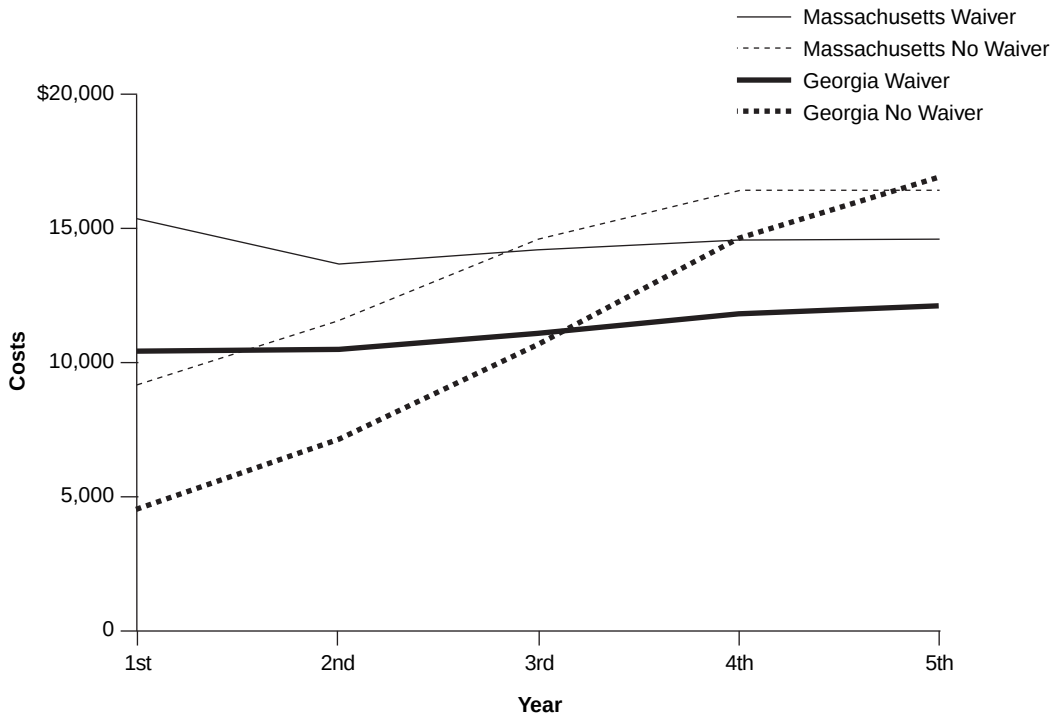
Annual Costs to All Payers

Figure 1 shows the annual average total treatment costs to the entire health care system for patients entering in the first year of the simulation for each of the waiver scenarios. Average costs in each year were calculated based on the number of patients alive in that year. In both States, the net cost of the demonstration to the health care system was highest in the first year after enrollment. In Georgia, the average cost in the first year was $10,300 in the waiver scenario and $4,800 in the no waiver scenario. In Massachusetts, the average cost in the first year was $15,100 in the waiver scenario and $9,100 in the no waiver scenario. The lower costs in Georgia were due to the savings in non-drug costs assumed in the Georgia application, the assumption that 15 percent of demonstration project enrollees would not immediately receive antiretroviral therapy in the Georgia waiver scenario, and the lower proportion of patients assumed to be receiving antiretroviral therapy in the Georgia no waiver scenario compared to the Massachusetts no waiver scenario.

In the fifth year after enrollment there was a net cost saving to the health care system for an average patient in both States, and the no waiver scenario cost was higher in Georgia than in Massachusetts. In Georgia, the average cost in the fifth year

Figure 1

Annual Average Treatment Costs for Patients in Massachusetts and Georgia Section 1115 Waiver Demonstrations Projects, by Enrollment Year



NOTE: 1999 constant dollars.

SOURCE: Schackman, R., Weill Medical College of Cornell University, Freedberg, K.A., Goldie, S.J., Swartz, K., Harvard School of Public Health, Freedberg, K.A., is also with Massachusetts General Hospital and the Harvard Medical School.

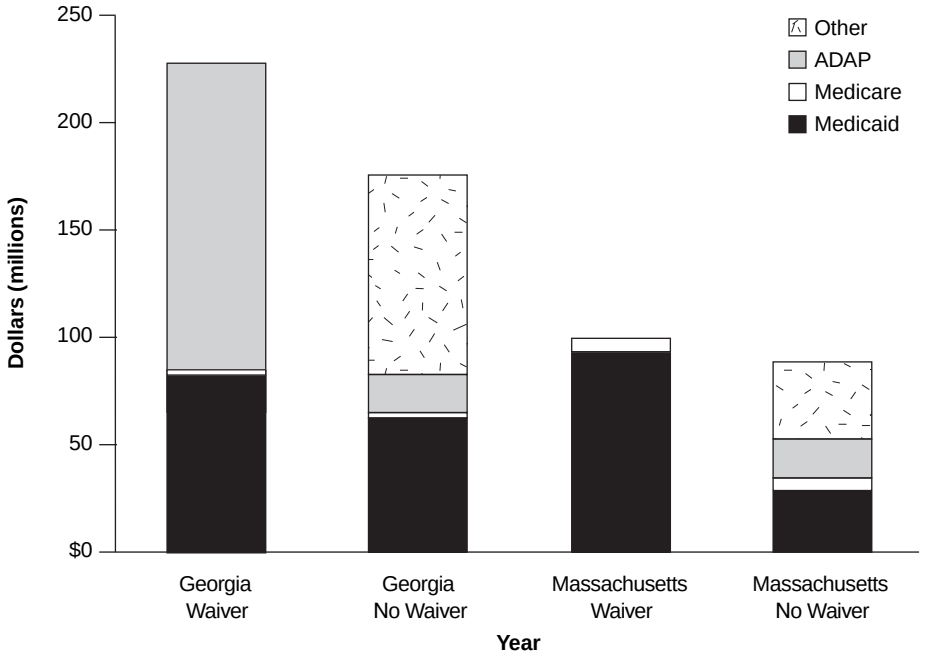
was $12,300 in the waiver scenario and $17,200 in the no waiver scenario. In Massachusetts the average cost in the fifth year was $14,500 in the waiver scenario and $16,000 in the no waiver scenario. These shifts occurred because patients who did not initiate early antiretroviral therapy subsequently had more HIV-related illnesses, and therefore had higher non-drug treatment costs in the fifth year than patients receiving early therapy. More patients in the Georgia no waiver scenario did not initiate early antiretroviral therapy than in the Massachusetts no waiver scenario, and non-drug costs were assumed to be higher in Georgia than in Massachusetts as a result of longer hospital LOS.

Allocation of Costs by Program

Figure 2 shows the allocation of costs by program, including both State and Federal contributions, when cohorts of patients entering in subsequent years were added to project the total costs of the demonstration projects over 5 years. In the Georgia waiver scenario, 65 percent of the 5-year costs were incurred by ADAP and 35 percent by Medicaid. In the Georgia no waiver scenario, 53 percent of the 5-year costs were incurred in the "other" category, 36 percent by Medicaid, and 11 percent by ADAP. In the Massachusetts waiver scenario, Medicaid incurred almost all of the costs. In the Massachusetts no waiver scenario, 40 percent of the 5-year costs were

Figure 2

Allocation of Costs (State and Federal Contributions) per Patient Over the 5-Year Demonstration Period: Georgia and Massachusetts



NOTES: 1999 constant dollars. ADAP is AIDS Drug Assistance Program.

SOURCE: Schackman, R., Weill Medical College of Cornell University, Freedberg, K.A., Goldie, S.J., Swartz, K., Harvard School of Public Health, Freeberg, K.A., is also with Massachusetts General Hospital and the Harvard Medical School.

incurred in the "other" category, 35 percent by Medicaid, and 22 percent by ADAP. In neither Georgia nor Massachusetts did Medicare play a major role in the first 5 years. Even if Medicare had provided a drug benefit that covered all of the Medicare enrollees' drug costs, the share of total costs allocated to Medicare in the first 5 years would have been less than 1 percent in Georgia and less than 8 percent in Massachusetts. This is due to the 29-month delay after Medicaid enrollment based on disability before patients can become eligible for Medicare.

Federal Budget Impact

Table 2 summarizes the projected 5-year net impact of the demonstration projects on the Federal Medicaid, ADAP, and Medicare budgets. In Georgia, the projected Federal Medicaid cost was $10.24 million, the projected Federal ADAP cost was $114.29 million, and the projected Federal cost for all three programs was $124.70 million. In Massachusetts, the projected Federal Medicaid cost was $33.72 million. Because the projected Federal contribution to ADAP would be reduced by $13.12 million and to Medicaid would be reduced by $1.12 million, the projected Federal cost for all three programs was $19.47 million.

Table 3 summarizes the results of sensitivity analyses. First, we considered scenarios in which the efficacy of first and second-line antiretroviral treatment was reduced from the level observed in clinical trials (Staszewski et al., 1999; Hammer et al., 1997) to the level reported in an observational study conducted at an urban clinic

Table 2

Projected 5-Year Net Federal Costs[1] of Section 1115 Demonstration Projects, by State

State	Year 1	2	3	4	5	1-5
Georgia						
Medicaid	$2.27	$6.74	$2.38	$4.12	$-5.27	$10.24
Medicare	—	—	0.03	0.11	0.04	0.18
ADAP	5.05	18.09	19.31	34.99	36.84	114.29
Total	7.32	24.83	21.72	39.22	31.62	124.70
Massachusetts						
Medicaid	7.83	7.10	6.45	6.04	6.29	33.72
Medicare	—	—	0.08	-0.16	-1.04	-1.12
ADAP	-2.46	-2.72	-2.74	-2.64	-2.55	-13.12
Total	5.37	4.38	3.79	3.23	2.70	19.47

[1] 1999 constant dollars (in millions).

NOTES: Federal share of Medicaid costs of 60.5 percent and Federal share of AIDS Drug Assistance Program (ADAP) costs of 90.1 percent is assumed for Georgia. Federal share of Medicaid costs of 50 percent and Federal share of ADAP costs of 76.9 percent is assumed for Massachusetts.

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in Maryland for which Medicaid is the principal insurer (Lucas, Chaisson, and Moore, 1999; Gebo et al., 1999). The result was a reduction from the base case in the projected 5-year cost for the combined Federal Medicaid, ADAP, and Medicare budget of $4.04 million in Georgia and of $0.53 million in Massachusetts. This reduction was due to a shorter projected time on antiretroviral therapy, based on the poorer treatment results reported for the Maryland Medicaid population compared to the clinical trial. The allocation of costs among programs was relatively consistent with the base case.

We also separately considered the effect of a 20-percent reduction in antiretroviral drug costs below the discounted price to government payers that was assumed in the base case. The projected 5-year impact on the combined Federal Medicaid, ADAP, and Medicare budgets was a reduction in costs of $20.89 million in Georgia and of $1.61 million in Massachusetts. In each State savings were realized by the program that incurred the cost of antiretroviral drugs in the waiver scenario (ADAP in Georgia, Medicaid in Massachusetts). These savings were partially offset by the loss of some savings that the alternative program (Medicaid in Georgia, ADAP in Massachusetts) would have realized as a result of the waiver in the base case.

Finally, we examined scenarios that were specific to each State. In Massachusetts, if enrollment was capped in the waiver scenario after the fourth year, as occurred in Georgia, the projected 5-year net cost to the combined Federal Medicaid, ADAP, and Medicare budgets declined by $0.57 million compared to the base case. In Georgia, if we assumed all HIV-infected patients were diagnosed and treated in accordance with Federal guidelines at the time that they entered the health care system, the net cost to the combined Federal Medicaid, ADAP, and Medicare budgets declined by $12.41 million compared to the base case. This was because the no waiver scenario costs increased faster than the waiver scenario costs, since more patients in the health care system were not currently being treated

Table 3

Sensitivity Analysis Results for Net 5-Year Federal Costs[1] of Section 1115 Demonstration Projects, by State

	Net 5-Year Cost		Compared to Base Case	
	Georgia	Massachusetts	Georgia	Massachusetts
Reduced Treatment Efficacy				
Total	$120.67	$18.94	$-4.04	$-0.53
Medicaid	10.77	32.44	0.54	-1.27
Medicare	0.17	-1.09	-0.01	0.03
ADAP	109.72	-12.41	-4.57	0.71
Additional 20% Antiretroviral Drug Discount[2]				
Total	103.81	17.86	-20.89	-1.61
Medicaid	12.26	29.61	2.02	-4.11
Medicare	0.18	-1.16	0.00	-0.04
ADAP	91.37	-10.59	-22.91	2.53
Enrollment Capped After the Fourth Year[3]				
Total	124.70	18.90	—	-0.57
Medicaid	10.24	32.88	—	-0.83
Medicare	0.18	-1.12	—	0.00
ADAP	114.29	-12.86	—	0.26
All Patients in Health Care System Treated According to Federal Guidelines[4]				
Total	112.30	19.47	-12.41	—
Medicaid	8.24	33.72	-1.99	—
Medicare	0.13	-1.12	-0.04	—
ADAP	103.92	-13.12	-10.37	—
No Non-Drug Cost Savings (Waiver Scenario)[4]				
Total	136.89	19.47	12.18	—
Medicaid	22.25	33.72	12.01	—
Medicare	0.35	-1.12	0.17	—
ADAP	114.29	-13.12	0.00	—

[1] 1999 constant dollars (in millions).

NOTES: Federal share of Medicaid costs of 60.5 percent and Federal share of AIDS Drug Assistance Program (ADAP) costs of 90.1 percent is assumed for Georgia. Federal share of Medicaid costs of 50 percent and Federal share of ADAP costs of 76.9 percent is assumed for Massachusetts.

[2] Reduced efficacy levels were determined by comparing the results of the ACTG 320 trial (Hammer et al., 1997) with the results reported in an observational cohort study of a Medicaid population in Maryland (Lucas, Chaisson, and Moore, 1999).

[3] Same as base case for Georgia.

[4] Same as base case for Massachusetts.

SOURCE: Schackman, R., Weill Medical College of Cornell University, Freedberg, K.A., Goldie, S.J., Swartz, K., Harvard School of Public Health, Freedberg, K.A., is also with Massachusetts General Hospital and the Harvard Medical School.

according to guidelines in the no waiver scenario. If no additional cost savings due to higher quality of care were assumed in the Georgia waiver scenario, the net Federal costs for the three programs increased by $12.18 million compared to the base case, mostly due to higher costs incurred by Medicaid.

DISCUSSION AND POLICY IMPLICATIONS

Costs of Section 1115 HIV Waivers

In an analysis of two Section 1115 demonstration applications, we found that neither the Georgia nor the Massachusetts

demonstration project was projected to meet 5-year tests of no increase in Federal spending over and above what would be expected in the absence of the demonstration either for Medicaid alone or for Medicaid, Medicare, and ADAP together. These results are consistent with previous analyses using the same model that found early HIV treatment was cost effective ($17,300 per quality-adjusted life year saved), but increased 5-year budgetary costs (Schackman et al., 2001). In Georgia, the 5-year cost increase associated with the waiver was much higher for Medicaid, Medicare, and ADAPs than for Medicaid alone ($124.70 versus $10.24 million). In Massachusetts, the 5-year cost increase using the broader definition was lower than for Medicaid alone ($19.47 versus $33.72 million).

Results were sensitive to different assumptions about access to treatment with and without the waiver and about savings associated with a projected increase in quality of care in Georgia. The institution of an enrollment cap in the fourth year was an additional factor that may have limited the total cost of the Georgia demonstration project, although instituting a similar cap in Massachusetts would not have resulted in substantial 5-year cost savings. In both States the demonstration projects led to substantial projected savings in other patient care costs not assigned to ADAP, Medicaid, or Medicare. These potential savings might affect budgets of State or local programs that provide care for uninsured HIV-infected patients, but were unlikely to have a substantial impact on the Federal budget.

Limitations

Our projections were derived from a simulation model of the progression of HIV disease that uses data from published studies in which participants may have different characteristics than Medicaid waiver enrollees and that may not fully reflect current treatment patterns. However, when the efficacy of antiretroviral therapy was reduced based on results reported for a Medicaid population, cost estimates changed, but our overall findings remained consistent.

We used average annual costs per patient predicted by our model for each treatment strategy in order to forecast total costs. This approach did not account for the possibility that patients in the no waiver scenarios enrolling in government programs had more severe symptoms (and higher than average costs) than patients in the waiver scenarios at the same stage of disease. Thus, we may have overestimated the net costs associated with the waivers. Some differences between the States may be due to assumptions in the waiver applications that were not independently validated, such as the stage of disease at cohort entry and associations between non-drug costs and hospital LOS or use of Centers of Excellence. We did not have access to State-level data to validate these assumptions, although some were tested in sensitivity analyses. Regional practice variations, such as reductions in Medicaid reimbursement in Georgia in the years immediately prior to the demonstration application, and differences in institutional settings between the States may also not be accurately captured. Both the budget forecasts in the waiver applications and our projections did not take account of possible future innovations in HIV treatment, such as the introduction of more effective and more expensive antiretroviral drugs.

Our alternative definition of 5-year Federal budget impact considered only direct health care costs incurred by Medicaid, Medicare, and ADAPs. We did not consider any additional impact of the

demonstration projects on the Federal budget for programs funded by the Ryan White CARE Act other than ADAPs, because no changes in these programs were indicated in the waiver applications, nor did we consider the possibility of crowd-out of private insurance coverage. Private insurance coverage in this population is relatively rare: 0 percent of Georgia and 11 percent of Massachusetts ADAP clients had private insurance coverage in 1999 (Doyle and Jefferys, 2000). We also did not consider non-health care cost budgetary effects, including possible savings to Supplemental Security Income or Social Security Disability Income programs and the tax effects of potentially increased levels of employment among enrollees in the demonstration projects (Goldman et al., 2001).

Policy Implications

New treatments can dramatically improve the length and quality of life for many patients with chronic diseases. As government payers seek to redesign programs in order to provide better coverage to chronic disease patients who lack access to private health insurance, there are several lessons to be learned from this analysis. First, a 5-year timeframe for measuring budget impact is likely to be unrealistic for many early medical interventions to treat chronic progressive diseases. For these diseases, cost savings are often realized over a longer period of time. Clinically-based models of disease progression and treatment, such as the model used in this study, can identify longer term costs and benefits. Second, under the current method of determining budgetary effects of program expansions, there is an incentive to cap enrollments in order to avoid an increase in Federal spending over and above what would be expected, at the cost of creating differences in treatment access between current and future patients. This incentive could be avoided by separately assessing annual costs for each year's enrollees.

In addition, the separate assessment of the budgetary effects on individual program budgets can make it more difficult to justify demonstrations that may achieve important policy objectives if they increase spending for any single program, even if they actually reduce overall government spending. Broader interpretation of this criterion would provide more opportunities to make budgetary tradeoffs elsewhere in the system, as Massachusetts was able to do within in its existing Medicaid demonstration project budget. However, the appropriate level of budgetary analysis at the Federal level is subject to debate because the Federal tax burden varies among programs depending on their funding sources (such as general revenue, FICA, or disability premiums). The impact of considering broader Federal budgetary effects therefore, depends on the program's source of funding and the timeframe for examining the impact. For instance, in this analysis the effects of the demonstrations on the Federal contribution to ADAP were large, but the impact on the Medicare budget was small. Non-health care budget effects were not analyzed, but it would be expected that savings in Federal Supplementary Security Income and Social Security Disability Income payments would be more important than enhanced Federal tax revenues because the program is targeted at low income enrollees. Medicaid coverage expansions for the elderly or higher-income working populations with other chronic diseases are likely to affect these Federal budget components in different ways.

Finally, analysis of the overall budget impact of State-initiated programs must be considered in the context of the complex interactions among Federal, State, and local health care budgets. Differences by health care program in cost sharing among levels of government can lead to gaming, as has been observed in mental health programs (Frank and McGuire, 1996). Because Federal-State cost-sharing ratios vary by State as well as by program, incentives to pursue the same health care coverage expansion initiative will vary among States (Schackman et al., 2001). Moreover, a large proportion of the potential savings from a health care coverage expansion may be in costs that are currently incurred as indigent or uncompensated care at the local level. By considering these multiple perspectives, it will be possible to conduct more comprehensive assessments of the budget impact of State-initiated programs such as Section 1115 demonstrations that are designed to improve access to cost-effective health care services in the U.S.

ACKNOWLEDGMENTS

The authors thank Michael Isbell, Jack Rodgers, and Rebecca Yip for assistance with the Georgia Section 1115 waiver; Runa Islam, April Kimmel, Elena Losina, and Hong Zhang for assistance with the Cost-Effectiveness of Preventing AIDS Complications (CEPAC) simulation model and project; Kawai Oneda for research assistance; and A. David Paltiel and colleagues for comments on an oral presentation of a previous version of this article.

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